US ERA ARCHIVE DOCUMENT

DATA EVALUATION RECORD § 72-2 - ACUTE EC 50 TEST WITH A FRESHWATER INVERTEBRATE

1. CHEMICAL: Metolachlor

PC Code No.: 108801

2. TEST MATERIAL: CGA-354743 (metolachlor metabolite)- 95% pure

3. CITATION: Author: C. Neumann

Title: Acute Toxicity Test of CGA 354743 (Metabolite of CGA 24705) to the Cladoceran

Daphnia magna STRAUS Under Static Conditions

Study Completion Date: October 28, 1996

Laboratory: Ciba-Geigy Limited, Basle, Switzerland

Sponsor: Novartis Crop Protection, Inc., Greensboro, NC

Laboratory Report ID: 961528

MRID No.: 449317-03 DP Barcode: D260392

4. REVIEWED BY: Mark Mossler, M.S., Environmental Scientist,

Golder

Associates Inc.

Signature:

Date:4/13/00

APPROVED BY: Pim Kosalwat, Ph.D., Senior Scientist,

Golder Associates Inc.

Signature:

Date:

5. APPROVED BY: Brian Montague, Fisheries Biologist

ERB I, Environmental Fate and Effects Division

Signature:

Date: 5/15/00

6. STUDY PARAMETERS:

Age of Test Organism:<24 hours **Definitive Test Duration:**48 hours

Study Method: Static

Type of Concentrations: Mean measured

7. <u>CONCLUSIONS</u>: This study is scientifically sound and fulfills the guideline requirements. The 48-hour EC₅₀ value of >108 ppm ai classifies the test material as practically non-toxic to *Daphnia magna*.

Results Synopsis:

EC₅₀: >108 ppm ai

95% C.I.: N/A

Probit Slope: N/A

NOEC: 108 ppm ai

8. ADEQUACY OF THE STUDY:

A. Classification: Core

B. Rationale: N/A

C. Repairability: N/A

9. GUIDELINE DEVIATIONS:

- 1. The hardness of the medium (234 mg/L as CaCO₃) was greater than the recommended maximum (200 mg/L as CaCO₃).
- 2. Temperature was only measured at test initiation and termination. Guidelines require hourly measurement for test systems controlled by room temperature.
- 3. Mortality during acclimation period not reported.

10. SUBMISSION PURPOSE:

11. MATERIALS AND METHODS:

A. Test Organisms

Guideline Criteria	Reported Information	
Species Preferred species is Daphnia magna	Daphnia magna	
All organisms are approximately the same size and weight?	Not reported	
<u>Life Stage</u> Daphnids: 1 st instar (<24 h).	1 st instar (<24 h)	
Supplier	In-house cultures	
All organisms from the same source?	Yes	

B. Source/Acclimation

Guideline Criteria	Reported Information
Acclimation Period Minimum 7 days	Culture and testing conditions were similar.

Guideline Criteria	Reported Information
Wild caught organisms were quarantined for 7 days?	N/A
Were there signs of disease or injury?	Not reported
If treated for disease, was there no sign of the disease remaining during the 48 hours prior to testing?	Not treated for disease
Feeding No feeding during the study.	No feeding performed during the study
Pretest Mortality No more than 3% mortality 48 hours prior to testing.	Not reported

C. Test System

Guideline Criteria	Reported Information
Source of dilution water Soft reconstituted water or water from a natural source, not dechlorinated tap water.	Elendt's M-4 medium
Does water support test animals without observable signs of stress?	Yes
Water Temperature Daphnia: 20°C Amphipods and mayflies: 17°C Midges and mayflies: 22°C Stoneflies: 12°C	22°C
pH Prefer 7.2 to 7.6.	8.2 - 8.4
Dissolved Oxygen Static: ≥ 60% during 1 st 48 h and ≥ 40% during 2 nd 48 h, flow-through: ≥ 60%.	≥97% of saturation
Total Hardness Prefer 40 to 200 mg/L as CaCO ₃ .	234 mg/L as CaCO ₃

Guideline Criteria	Reported Information
Test Aquaria	
1. <u>Material:</u> Glass or stainless steel.	Glass
2. <u>Size</u> : 250 mL (daphnids and	150-mL
midges) or 3.9 L (1 gal).	150-11112
3. <u>Fill volume</u> : 200 mL (daphnids and midges) or 2-3 L.	100 mL
Type of Dilution System Must provide reproducible supply of toxicant.	N/A ~
Flow Rate Consistent flow rate of 5-10 vol/24 hours, meter systems calibrated before study and checked twice daily during test period.	N/A
Biomass Loading Rate	:
Static: ≤ 0.8 g/L at $\le 17^{\circ}$ C, ≤ 0.5 g/L at $\ge 17^{\circ}$ C; flow-through: ≤ 1 g/L/day.	1 daphnid/20 mL
Photoperiod	
16 hours light, 8 hours dark.	16 hours light, 8 hours dark
Solvents	
Not to exceed 0.5 mL/L for static tests or 0.1 mL/L for flow-through tests.	Solvent: none Maximum conc.: N/A
IIII/L for now-unough tests.	IVIAAIIIUIII COIIC IV/A

D. Test Design

Guideline Criteria	Reported Information	
Range Finding Test If EC ₅₀ >100 mg/L, then no definitive test is required.	Concentrations were selected based upon a range finding test	
Nominal Concentrations of Definitive Test Control & 5 treatment levels; a geometric series with each concentration being at least 60% of the next higher one.	Control, 10, 18, 32, 58, and 100 mg/L, not corrected for active ingredient (ai)	

Guideline Criteria	Reported Information
Number of Test Organisms Minimum 20/level, may be divided among containers.	20, 5 per replicate
Test organisms randomly or impartially assigned to test vessels?	Yes
Water Parameter Measurements 1. Temperature Measured continuously or, if water baths are used, every 6 h, may not vary > 1°C. 2. DO and pH Measured at beginning of test and ever 48 h in the high, medium, and low doses and in the control.	Temperature was measured at initiation and termination in the control and each treatment group. DO and pH were measured at initiation and termination in the control and each treatment group.
Chemical Analysis Needed if solutions were aerated, if chemical was volatile, insoluble, or known to absorb, if precipitate formed, if containers were not steel or glass, or if flow-through system was used	Samples of the exposure solutions were taken at time 0 and at termination. Samples were analyzed by HPLC.

12. <u>REPORTED RESULTS</u>:

A. General Results

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	Yes, but compliance was to Swiss and OECD GLPs
Control Mortality Static: ≤10% Flow-through: ≤5%	No immobilization in the control group
Percent Recovery of Chemical: 1) % of nominal; 2) Procedural recovery; 3) Limit of quantitation (LOQ)	100-109% of nominal, proc. recovery of 98%, LOQ = 0.1 mg/L

Guideline Criteria	Reported Information
Raw data included?	Yes

Analytical results

Nominal	Measured concentration (ppm a		
concentration (ppm)	0	48	
Control	<0.1	<0.1	
10	10.4	10.3	
18	18.7	18.5	
32	34.0	34.9	
58	57.9	58.9	
100	108	109	

Immobilization

Concentration	Number	Cumulative Number Immobilized		
Nominal	Mean Measured	of Organisms	Hour of	Study I
(ppm)	(ppm ai)		24	48
Control	<0.1	20	0	0
10	10	20	0	0
18	19	20	0	0
32	35	20	0	0
58	58	20	1	1
100	108	20	0	0

Other Significant Results: The immobility noted at the 58 ppm ai treatment level was not believed to be due to treatment.

B. Statistical Results

Method: visual interpretation (based on nominal conc.)

48-hr EC₅₀: >100 ppm

95% C.I.: N/A

Probit Slope: N/A

NOEC: 100 ppm

13. VERIFICATION OF STATISTICAL RESULTS: Lack of dose response precluded the use of statistics

Method: visual interpretation (based on mean measured conc.)

48-hr EC₅₀: >108 ppm ai

95% C.I.: N/A

Probit Slope: N/A

NOEC: 108 ppm ai

14. **REVIEWER'S COMMENTS:** This study is scientifically sound, fulfills the guideline requirements, and can be classified as **Core**. The 48-hour EC_{50} was determined to be >108 ppm ai, which classifies the test material as practically non-toxic to *Daphnia magna*.